REMARKS

Claims 14-20 are pending in the present application. Claim 20 is withdrawn as drawn to a non-elected species. Claim 14 is amended herein to incorporate the limitations of claim 15, and claim 15 is cancelled herein without prejudice.

Claim 17 stands rejected under 35 U.S.C. § 112, first paragraph, enablement. Claims 14-16 and 18-19 stand rejected under 35 U.S.C. § 103(a), non-obviousness. Each rejection is addressed below.

I. Rejection under 35 U.S.C. § 112, first paragraph, enablement

Claim 17 stands rejected under § 112, first paragraph, enablement. Pages 3-4 of the Office Action states that there are no working examples demonstrating the induction of a prophylactic immune response, which is interpreted broadly as merely requiring that one microorganism gain entry into the cells of a host. Applicants respectfully disagree.

The enablement requirement is met if the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, it has long been settled that, even in biotechnology, multiple examples are not essential to satisfy the enablement requirement. *In re Strahilevitz*, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982) (working examples are not required to satisfy enablement for immunological method of removing haptens from blood of a mammal).

Though working examples are not required, Applicants have provided a working example in the specification demonstrating the induction of a prophylactic immune response. Specifically, the data contained in Figure 6 of the patent application (Example 3) demonstrates that immunization with anthrax protective antigen (PA) and compound 48/80 induces antibodies that neutralize the toxicity of anthrax lethal toxin.

The Office Action also states that the specification does not adequately guide or direct the use of the method of claim 17. Applicants assert that the induction of a prophylactic or protective immune response is well-established in the patent literature. A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); see also MPEP § 2164.01.

For example, Claim 27 of Patent No. 7,217,791:

27. The method of claim 26, wherein the immune response is a ***prophylactic immune response***.

Claim 18 of Patent No. 6,890,538:

18. A method of generating a ***protective immune response*** to a herpes simplex virus (HSV) in a human or animal host, said method comprising: (a) providing an immunogenic composition; wherein said composition is comprised of an invasive but attenuated or non-pathogenic bacterium selected from the group consisting of Salmonella, Shigella, Listeria and E. coli bacteria; said bacterium is comprised of a coding sequence encoding a herpes simplex virus (HSV) antigen selected from the group consisting of glycoprotein D, glycoprotein H, glycoprotein B and ICP27; and said coding sequence is comprised within an expression construct and operably linked to one or more regulatory sequences and (b) administering said composition to said host such that said bacterium invades a host cell of said host selected from the group consisting of macrophages and dendritic cells and said expression construct is transferred into said host cell where said regulatory sequences direct expression of said coding sequence, and said HSV antigen is transcribed and translated in said host cell without introduction of an antimicrobial agent to lyse the bacterium to generate ***said prophylactic immune response*** against HSV.

A search of the issued patent literature revealed 119 patents with the term "protective immune response" in the claims. Examples include Claims 1 and 3 of Patent No. 7,258,863:

1. A method for providing a ***protective immune response*** in a subject in need of protection against Shigellosis caused by a first Shigella species comprising mucosally administering to the subject a vaccine comprising an isolated Shigella Invaplex 50, which contains LPS, IpaB, IpaC, IpaD, VirG 72 kDa and 84 kDa polypeptides, to induce a ***protective immune response*** against the first Shigella species, wherein the Shigella source for the Invaplex 50 is distinct from the first Shigella species and said administration is selected from the group consisting of oral, rectal, and intranasal.

3. The method according to claim 2 further comprising measuring for a ***protective immune response.***

and Claims 1 and 2 of Patent No. 7,255,862:

1. A vaccine that induces a ***protective immune response*** in a feline against homologous and heterologous feline immunodeficiency virus, comprising a carrier and an ALVAC recombinant poxvirus that consists essentially of, and expresses in vivo in a feline, nucleic acid molecules encoding FIV Gag and protease.

2. A method for inducing a ***protective immune response*** against FIV in a feline comprising administering to the feline the vaccine of claim 1.

In light of the above discussion, Applicants assert that there is no reason to doubt enablement is satisfied for claim 17, which is directed to inducing a prophylactic immune response (M.P.E.P. § 2164.04). Therefore Applicants respectfully request that the rejection of claim 17 under 35 U.S.C. § 112, first paragraph, be withdrawn.

II. Rejection under 35 U.S.C. § 103(a)

Claims 14-16 and 18-19 stand rejected under 35 U.S.C. § 103(a) over Mielcarek et al. (2001). The Office Action states that Mielcarek et al. teaches that compound 48/80 is a mast cell activator and that mast cells can efficiently phagocytose *B. pertussis*. The Office Action further states that Mielcarek et al. does not teach the administration of a mast cell activator, compound 48/80, with the immunogen to enhance the immune response against the antigen. The Office Action then states, "However, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to administer compound 48/80 with the immunogen to the mice." Applicants respectfully disagree.

To establish a prima facie case of obviousness, three requirements must be satisfied. First, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *See In re Wilson* 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art"). The teachings must come from the prior art, not from Applicants' disclosure. *See In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. *In re Oetiker,* 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992); *In re Fine*, 837 F.2d at 1074; *In re Skinner*, 2 U.S.P.Q.2d 1788, 1790 (Bd. Pat. App. & Int. 1986). Third, the proposed modification or combination of the prior art must have a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991).

First, Mielcarek et al. does not teach or suggest the simultaneous administration of compound 48/80 and an immunogen in the same carrier, which is recited in Applicants' claims. Instead, in Mielcarek et al., "mice were *pretreated* with the mast cell activator compound 48/80 *72 hr before* bacterial infection" in order to significantly reduce the number of resident mast cells and subsequently measure TNF-α production (page 184). Compound 48/80 was used to deplete the tissue of mast cells before infection (see also Summary section) and was therefore not used in the manner recited in Applicants' claims.

Second, given this pretreatment, Mielcarek et al. is clearly concerned with a different phenomenon, and therefore there is no suggestion or incentive given by the Mielcarek et al. reference that would have motivated one skilled in the art to modify the procedures used in Mielcarek et al. to simultaneously administer compound 48/80 and an immunogen in the same carrier to produce an immune response.

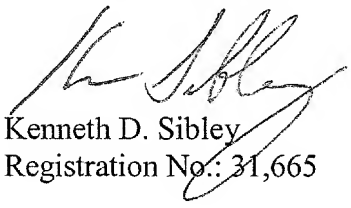
Third, Mielcarek et al. does not teach or suggest that the administration of compound 48/80 with an immunogen would activate an immune response. Thus there would be no reasonable expectation of success in inducing an immune response by simultaneously administering compound 48/80 and an immunogen using this reference. In fact, Mielcarek et al. teaches away from Applicants' claims by using compound 48/80 to deplete the mouse tissue of mast cells, which cells "may play a role in the induction of immune responses against *B. pertussis*" (Summary section).

Therefore the Mielcarek et al. reference cannot support a prima facie case of obviousness, and it is respectfully requested that this rejection of claims 14-16 and 18-19 under 35 U.S.C. § 103(a) be withdrawn.

III. Conclusion

In light of the above discussion, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,



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